Device Retrieval

In the event of sub-optimal deployment, the Occluder may be removed.

- Gently pull on Retrieval Cord to bring delivery system back into contact with the Occluder.
- Replace and tighten Red Retrieval Cord Cap to secure the Retrieval Cord.
- Loosen Gray Control Catheter Luer.
- Pull Gray Control Catheter back into the Green Delivery Catheter.
  - Keep tip of Green Delivery Catheter away from lock loop.
- Continue to unlock the Occluder until free of the septum.
- Once free, pull entire system to groin and complete removal by pulling through the sheath.

As long as the Occluder remains seated in the septum, the device will unlock and can be drawn into the Green Delivery Catheter. The operator must exercise care that the Green Delivery Catheter is withdrawn sufficiently to allow the locking loop to fully extend (Fig. D-14).

Once the Occluder is free of the septum, the locking loop will present higher resistance and could cause the Retrieval Cord to break. The operator is cautioned to draw the entire Occluder / delivery system assembly back to the introducer sheath before completing device retrieval.

Figure D-14

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Delivery System Removal

When satisfied with Occluder position, the delivery system can be removed.

- Ensure that the Red Retrieval Cord Cap has been removed.
  - Retrieval Cord is free on one end and looped through the right atrial eyelet.
- Unlock the Gray Control Catheter
- While holding the Gray Control Catheter, advance the Green Delivery Catheter such that it abuts the Occluder.
- Slowly pull the Gray Control Catheter until catheter and Retrieval Cord exit the delivery system.
  - Dedicated Retrieval Cord lumen prevents tangling with other components.
- Pull the Green Delivery Catheter until it exits the introducer sheath.

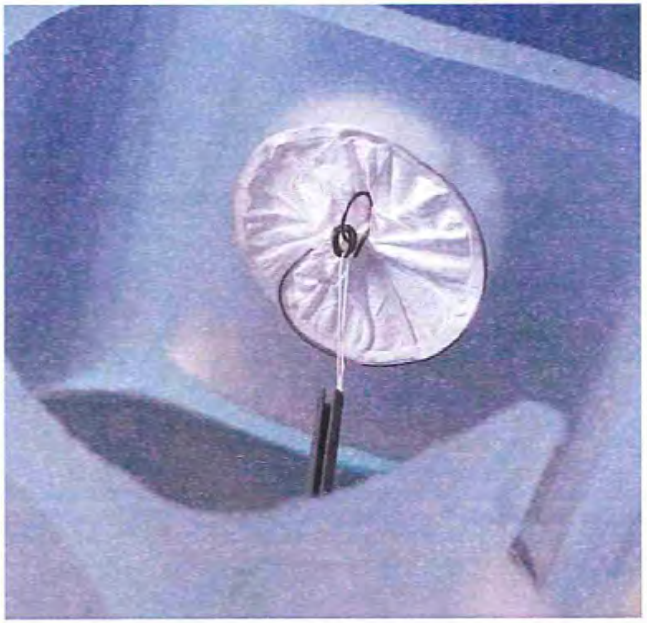

Figure D-15 — Retrieval Cord is free on one end and looped through the right atrial eyelet

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GORE HELEX SEPTAL OCCLUDER

Review

ALWAYS

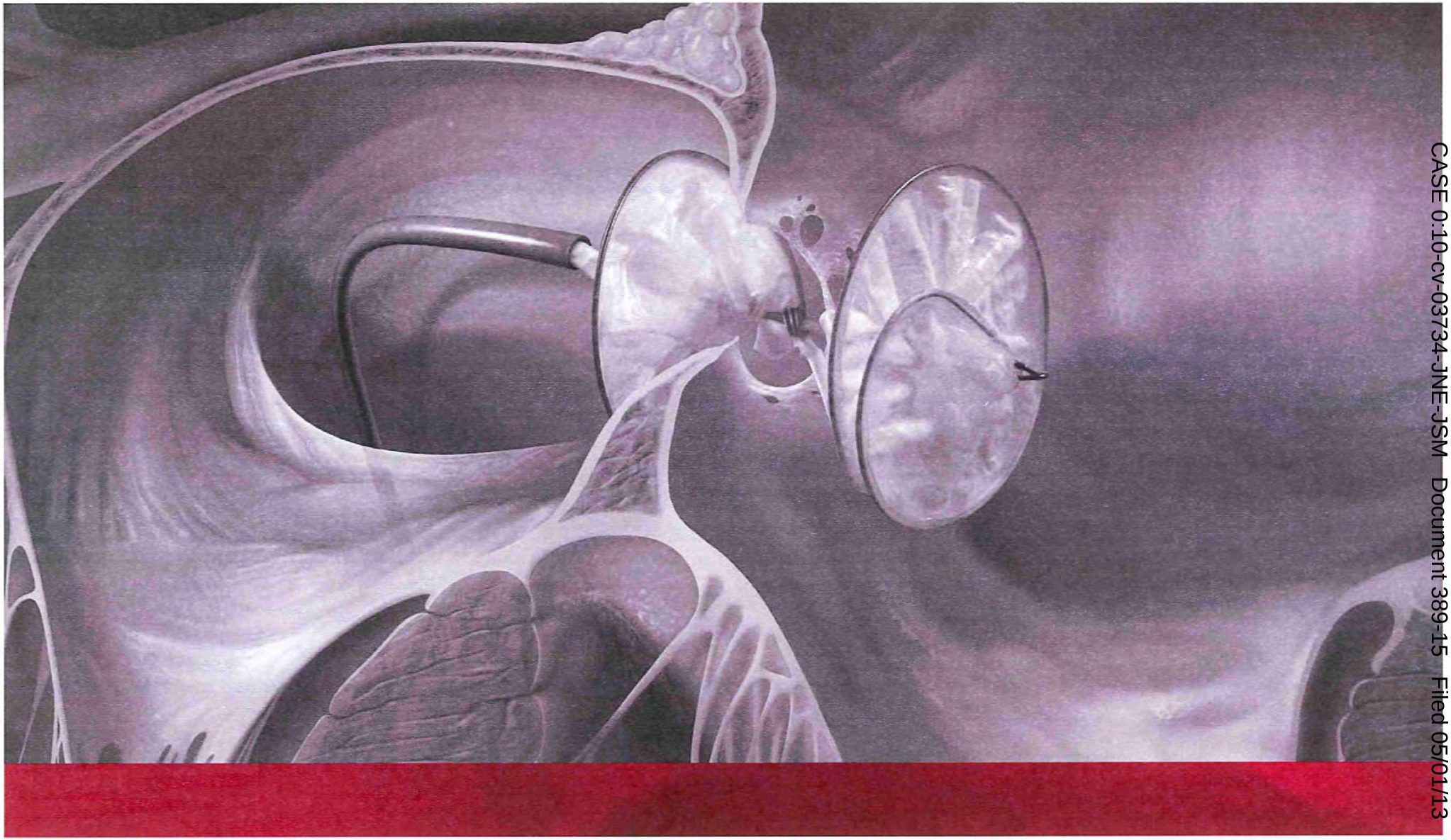
- Use a light touch.
- Move one component at a time.
- Lock the Mandrel Luer at completion of left atrial disc.
- Lock Gray Control Catheter Luer at completion of right atrial disc.
- Make smooth transition from left atrial disc to right atrial disc.
  - Appose left atrial disc gently to left septum.
  - Hold Gray Control Catheter.
  - Pull Green Delivery Catheter to prepare for right atrial disc deployment.

NEVER

- ***Never...*** Pull the left atrial eyelet against the Green Delivery Catheter.
  – Premature lock may result.
- ***Never...*** Pull the left atrial disc firmly against the septum.
  – Premature lock may result.
- ***Never...*** Push the Tan Mandrel.

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER



TIPS FOR SUCCESS

GORE HELEX SEPTAL OCCLUDER

Tips for Success

The GORE HELEX Septal Occluder is a compliant device that quickly forms to the shape of the heart, reducing the potential for erosion through delicate tissues. Consequently, the Occluder can be positioned to close some complex defects, such as those with deficient anterior-superior rims.

Though the GORE HELEX Septal Occluder is easy to deploy, there is a learning curve associated with achieving successful deployment.

The following sections elaborate on the Occluder design and describe some of the techniques that cardiologists have found useful to improve defect closure and take advantage of the unique characteristics of this device. These discussions will point out some of the more common issues a cardiologist may encounter during early use of the GORE HELEX Septal Occluder.

Premature Lock Release

When the product is assembled, the three eyelets are loaded onto the Tan Mandrel, the locking loop is straightened and placed within the lumen of the Tan Mandrel at the distal tip. The tip is then flared to hold the eyelets in position. Once the Occluder is fully deployed across the septal defect, the Tan Mandrel is withdrawn, pulling the Tan Mandrel's flared tip through the three eyelets. Upon release from the Tan Mandrel, the wire forms a loop and prevents the eyelets from escaping. Refer to the drawings on pages C-8 and C-9 to review product construction.

The distal eyelet could become dislodged during loading or during extended repositioning and lead to premature lock release. Inadvertent lock release during left atrial disc conformation can be prevented by maintaining 3 – 5 mm between the tip of the Green Delivery Catheter and the left atrial eyelet. Once the left atrial disc is formed and seated against the septum, only mild tension on the delivery system is necessary to keep the Occluder seated. Greater tension on the system may cause the disc to pull through the septum, or it may cause the lock mechanism to partially release.

Under high resolution fluoroscopy, the clinician may detect that the locking loop is no longer straight within the Green Delivery Catheter (Fig. E-1).

Under fluoroscopy, a device that has been released will appear out of position or "floppy." The operator will notice that the device no longer responds to Tan Mandrel manipulation (Figs. E-2 and E-3). Further delivery system manipulation will eventually result in full lock release. A prematurely released device must be removed and replaced with a new device.

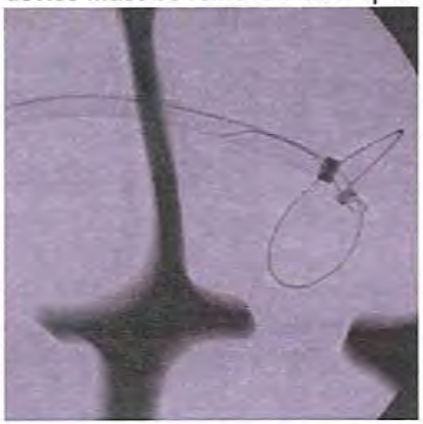


Figure E-1

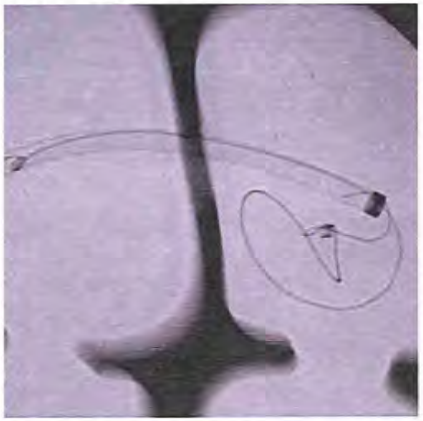


Figure E-2

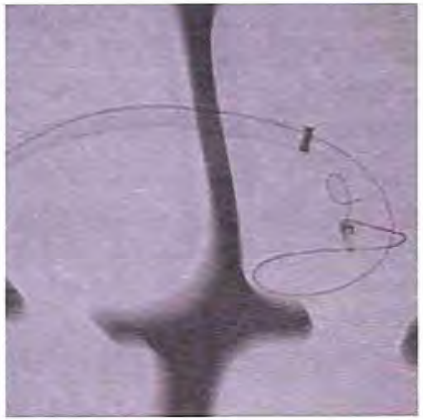


Figure E-3

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Kinked Tan Mandrel

The function of the Tan Mandrel is twofold; extension elongates the Occluder during loading or repositioning and withdrawal configures the discs. The Tan Mandrel is not radiopaque, however the Mandrel Stinner within the Tan Mandrel is visible under fluoroscopy. If the Tan Mandrel becomes kinked, the device will appear "off-center" with respect to the delivery system. Ciné will reveal that the Mandrel Stiffener and the locking loop are no longer alligned with the delivery system.

The kinked Tan Mandrel is corrected by withdrawing the Tan Mandrel until the device assumes normal configuration. Once the Tan Mandrel is straightened, the device should deploy normally. If deployment problems persist, the device and delivery system should be removed and a new device selected for use.

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"Missed" Right Atrial Eyelet

In an optimal deployment, the lock sets when the Tan Mandrel is removed, capturing all three eyelets. Inappropriate catheter manipulation or unexpected movement of the heart may result in failure to capture the right atrial eyelet. Ciné of the Occluder in side view will quickly reveal if all eyelets are captured (Fig. E-4). A slight tug on the Retrieval Cord will demonstrate whether the eyelet moves with the device or independent of the device.

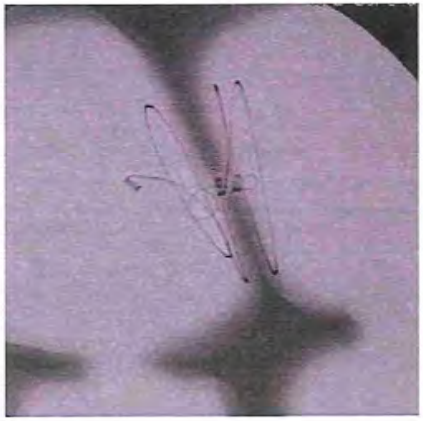

Figure E-4

Uneven Deployment

The Occluder is designed to provide one and one-quarter discs on each side of the defect, separated by the central (septal) eyelet. Inappropriate tension, improper sizing, or oddly shaped defects may cause more of the Occluder to be configured in either the left or the right atrium (note position of central eyelet). The Occluder may be easily repositioned to correct this problem by extending the Tan Mandrel and withdrawing the control catheter in small increments until sufficient device has been recovered to correct the deployment.

If an Occluder pulls through the defect repeatedly, there is a risk of embolization. The chosen device may be too small for the defect, or too large to properly configure within the atrium. An alternative device size should be utilized.

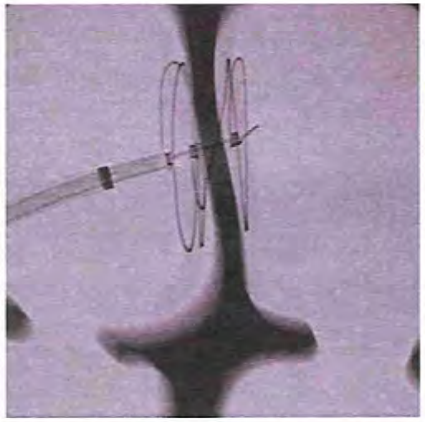

Figure E-5 — Deployment favors right atrium

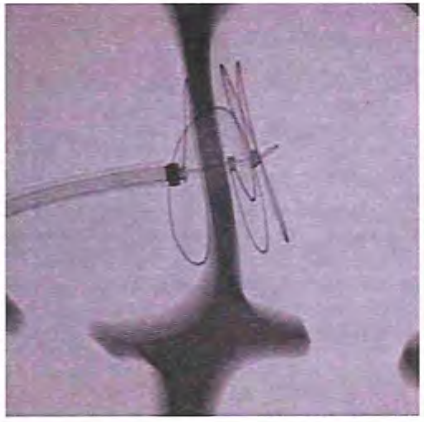

Figure E-6 — Deployment favors left atrium

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Broken Retrieval Cord

If, prior to final lock release, the Gray Control Catheter can be withdrawn without any corresponding motion of the Occluder, the clinician should suspect a broken or lost Retrieval Cord. Once the Retrieval Cord is broken or lost, standard interventional retrieval techniques (snares, retrieval baskets, etc.) must be employed should emergency recapture become necessary (see Embolization / Emergency Recapture, page E-10).

The simplest cause might be that the Red Retrieval Cord Cap has become loosened, allowing the cord to slip out of reach. The application of a Kelly forcep across the entire delivery system may allow the Retrieval Cord to be fixed and allow the unlocking and withdrawal of the Occluder to continue. Should the cord break during unlocking, the device is considered at risk for embolization; emergency recapture procedures should be prepared immediately. Replacement of the Red Retrieval Cord Cap following lock release will ensure that the Retrieval Cord is under control.

Improper "Feel"

Clinicians quickly become accustomed to the appropriate "feel" of the GORE HELEX Septal Occluder. Any significant change in the force required to manipulate the device should alert the operator to consider the following possibilities:

Repositioning

If the Occluder has been repositioned extensively during deployment or if the device was loaded using inappropriate force, the right atrial eyelet could have become elongated. Though mild elongation of the formed wire recovers without problem, the Retrieval Cord could become trapped or entangled within the windings. In that condition, the operator will feel greater than normal resistance when attempting to withdraw the Gray Control Catheter during final release. If such a condition is encountered, the operator should replace the Red Retrieval Cord Cap or otherwise gain control of the Retrieval Cord such that the Occluder can be retrieved using the delivery system.

Excessive Force Encountered During Unlocking

If an Occluder must be unlocked and removed, following either a successful lock release or one that failed to capture all eyelets, the Tan Mandrel can no longer provide alignment of the eyelets that would guide them back into the Green Delivery Catheter. The center eyelet may "snag" on the Green Delivery Catheter tip during recapture, and cannot be easily brought into the delivery catheter (Fig. E-7). Manipulation of the Green Delivery Catheter with mild tension on the septum may help bring the center eyelet into the Green Delivery Catheter. If the entire delivery system is withdrawn, the Occluder will continue to unlock, and can safely be withdrawn. It may be necessary to remove the device and the sheath together.

The Green Delivery Catheter must be withdrawn sufficiently during unlocking to allow the lock to fully extend (Fig. E-8) at each perforation in the ePTFE membrane and at each eyelet. Unlocking should always be performed under fluoroscopy at full magnification. Any extension of the eyelets, as shown in the accompanying image (Fig. E-9), indicates that too much force has been applied.

When excessive force is applied, the Retrieval Cord may break or the Occluder frame could fracture. In either case, embolization is possible.

Figure E-7

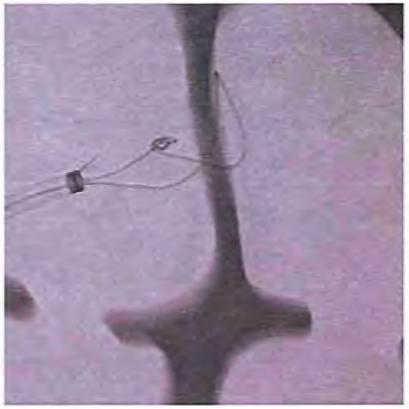

Figure E-8

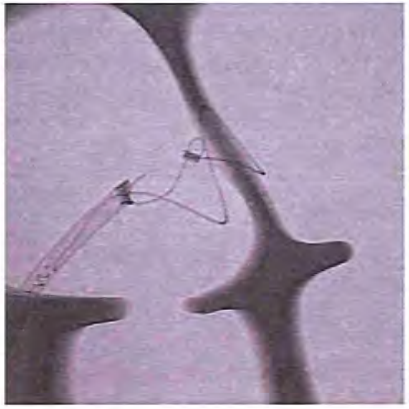

Figure E-9

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Embolization / Emergency Recapture

Should the Occluder embolize from the defect, or if control of the device is lost due to Retrieval Cord breakage or device fracture, it is recommended that a large diameter sheath (such as an 11 Fr Mullins-type sheath) be exchanged and brought as close to the device as possible. The Occluder can be snared easily and brought into a larger sheath. While snaring the right atrial eyelet would be optimal, snaring any portion of the device will likely result in successful recapture. It can be difficult to recapture an embolized device through the 10 Fr Green Delivery Catheter.

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Fluoroscopic Appearance

When deployed in a model having uniform dimensions, the Occluder appears planar and parallel (Fig. E-10). Notice that from the center eyelet the two radial arms are placed on opposite sides of the septum, the lock mechanism is straight as it aligns the eyelets and the lock loop is fully curled, capturing all three eyelets and securely locking the device in place.

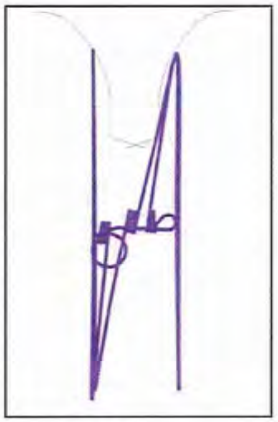

Figure E-10

Septal anatomy, however, seldom allows the Occluder to take on such a theoretically ideal shape after deployment. Variation in the thickness of the septum and the proximity of the defect to other cardiac structures may cause the two discs to appear distinctly non-parallel (Figs. E-11 thru E-13). Apposition to the septum is more important than fluoroscopic appearance. A successful implant should rest in a planar condition relative to the septum. The position can be confirmed by TEE / ICE or by angiography. A right atrial or pulmonary artery contrast injection with observation of the levophase is used to illustrate left and right septal planes and to confirm that the Occluder is well apposed.

Devices should be removed if:

- An excessive shunt persists
- The discs are not apposed to the septum
- The right atrial eyelet was not captured

Keep in mind that the disc-to-disc spacing usually becomes smaller in the first 30 minutes following deployment as the Occluder "settles" into place and further conforms to the cardiac anatomy.

Figure E-11

Figure E-12

Figure E-13

Consult Instructions for Use

GORE HELEX SEPTAL OCCLUDER

Suggested Reading

Atrial Septal Defect References

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2. Hein R, Büscheck F, Fischer E, *et al*. Atrial and ventricular septal defects can safely be closed by percutaneous intervention. *Journal of Interventional Cardiology* 2005;18(6):515-522.
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6. Smith BG, Wilson N, Richens T, Knight WB. Midterm follow-up of percutaneous closure of secundum atrial septal defect with Helex Septal Occluder. *Journal of Interventional Cardiology* 2008;21(4):363-368.
7. Fagan T, Dreher D, Cutright W, Jacobson J, Latson L; GORE HELEX Septal Occluder Working Group. Fracture of the GORE HELEX Septal Occluder: associated factors and clinical outcomes. *Catheterization & Cardiovascular Interventions* 2009;73(7):941-948.

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